EXHIBIT B

Class 1 Device Recall Medtronic HeartWare HVAD System

Class 1 Device Recall Medtronic HeartWare HVAD System

See Related Information[22]

Date Initiated by Firm	May 02, 2018
Date Posted	May 21, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-1903-2018
Recall Event ID	80056[23]
PMA Number	P100047[24]
Product Classification	Ventricular (assist) bypass[25] - **Product Code** DSQ[26]
Product	Heartware Medtronic HVAD System for cardiac use. Including the following parts: (a) Controller / Controller Kits, Product numbers: 1400, 1401, 1403, 1407, 1420 (b) DC Adapter, Product numbers: 1435, 1440 (c) AC Adapter, Product numbers: 1425, 1430 (d) Battery Pack, Product number: 1650DE Indication for Use for OUS HVAD System: The HVAD System is intended for use in patients at risk of death from refractory end-stage heart failure. The HVAD System is designed for in-hospital and out-of-hospital settings, including transportation via fixed wing aircraft or helicopter.
Code Information	ALL SERIAL NUMBERS UPN/GTIN: (a) 1400 and 1401: distributed prior to GTN requirement 1403: 00888707000116, 00888707000475 1407: '00888707000291, '00888707000727, '00888707000710, 00888707000734, '00888707000741, '00888707000765, '00888707000758, '00888707000789, '00888707000772, '00888707000499, '00888707000796, '00888707000802, '00888707000819, '00888707000482, '00888707004534, '0888707001670, '00888707001656, '00888707001663, '00888707001670, '00888707001687, '00888707001694, '00888707001700, '00888707001717, '00888707001724, '00888707001731, '00888707001748, '00888707001755, '00888707001762, '00888707002813, '00888707002820, '00888707002837, '00888707002844, '00888707002851, '00888707001472 1420: '00888707000420, '00888707000437, '00888707002660 (b) 1435: '00888707000109 1440: '00888707000260, '00888707001885, '00888707001496, '00888707002745 (c) 1425: '00888707000093 1430: '00888707000307, '00888707000826, '00888707000833, '00888707000840, '00888707000857, '00888707000871, '00888707000864, '00888707000888, '00888707000901, '00888707000505, '00888707000895, '00888707000918, '00888707001489, '00888707001779, '00888707001786, '00888707001793, '00888707001809, '00888707001816, '00888707001823, '00888707001830, '00888707001847, '00888707001854, '00888707001861, '00888707001878, '00888707002738, '00888707002769, '00888707002776, '00888707002783, '00888707002790, '00888707002806, '00888707004817 (d) 1650DE: 00888707000369, 00888707001373, 00888707001588, 00888707001366, '00888707002684 '00888707002646, '00888707002653, '00888707000376
Recalling Firm/ Manufacturer	Heartware 14400 NW 60th Ave Miami Lakes FL 33014-2807
For Additional Information Contact	877-367-4823
Manufacturer Reason	Possible transient electrical connection interruption between an HVAD System power source (Battery, AC Adapter, or

for Recall	DC Adapter) and the Controller, while the power source is connected, that may cause unintended switching to the secondary power source and/or unexpected audible tones (beeping). The interruption typically lasts 1-2 seconds, due to oxidation between power source connector and socket.
FDA Determined Cause [2]	Device Design
Action	The firm notified physicians and healthcare professionals about the device correction by letter on 05/02/2018. The letter explained problem and provided recommendations for effective power source management of the system. Medtronic began notifying VAD Clinicians in the US on May 31, 2018, mainly via 2-day courier, and OUS via locally approved methods, of a newly available field service. A field service for application of a lubricant to the HVAD System power source connectors to mitigate the potential for transient interruptions of the electrical connection between an HVAD System power source (Battery, AC Adapter, or DC Adapter) and the HVAD Controller is now available.
Quantity in Commerce	175878 devices
Distribution	Worldwide Distribution including US Nationwide, Argentina, Australia, Austria, Belarus, Belgium, Brazil, Canada, Chile, Croatia, Cyprus, Czech Republic, Denmark, Egypt, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, India, Israel, Italy, Japan, Kazakhstan, Korea, , Kuwait, Latvia, Lebanon, Lithuania, Luxembourg, Malaysia, Netherlands, New Zealand, Norway, Poland, Romania, Saudi Arabia, Serbia, Singapore, Slovakia, South Africa, Spain, Sweden, Switzerland, Taiwan, Turkey, Ukraine, United Arab Emirates, and Vietnam.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

PMA Database	PMAs with Product Code = DSQ and Original Applicant = Medtronic[29]

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15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
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20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=80056
24. /scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P100047
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DSQ
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DSQ
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=DSQ
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMA/pma.cfm?start_search=1&productcode=DSQ&applicant=Medtronic

Page Last Updated: 01/18/2020

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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=80056

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